3. Remarks

A. Election/Restriction

Applicants have cancelled claims 72 and 74.

B. Rejection under 35 U.S.C. § 112

The Examiner rejected claims 10, 20, 69, and 102 under 35 U.S.C. § 112 as being indefinite. In response, Applicants have requested amendment of these claims to remove "and/or", modify the dependency, and provide antecedent bases. Applicants have also requested an amendment of claim 70 to correct dependency in a manner similar to the correction in Claim 69.

C. Double Patenting

Claim 63 has been cancelled.

D. Rejection of Claims under 35 U.S.C. § 102

The Examiner has rejected claims 1, 3, 61 and 102 - 103 under 35 U.S.C. § 102 as being anticipated over **Koch** (U.S. Pat. No. 4,465,067). The Examiner states that **Koch** discloses a method for delivering a therapeutic gas, oxygen, to a person having a nasal/oral mucus membrane, which comprises generating a flow of the gas and infusing the nasal or oral mucus membrane, wherein the person refrains from inhaling. The Examiner states that "by dint of anatomy" both the nasal and oral cavities will be infused when gas is delivered to one.

Applicants note that Claim 1 has been amended to clarify that the person refrains from inhaling *the therapeutic gas*.

Koch discloses a device for oxygen insufflation. Significantly, **Koch** specifically states that the device's purpose is to improve the patient's *breathing*. (See, e.g., Col. 1, Line 56; Col 2, Lines 43 - 46). Nowhere in **Koch** is there a suggestion that the while the oxygen is "blown into .. one nostril" (Col. 2, Line 17) the patient should refrain from inhaling the therapeutic gas, as is required in Claims 1 and 103, or inhibit the passage of the therapeutic gas into the trachea and lung by limiting inhalation, as is required by Claims 61 and 102.

The Examiner's statement that "the gas is delivered to insufflate the oronasal cavity, hence delivery is not primarily for breathing but insufflation, if the user where to breath the gas could not insufflate the nasal cavity [sic]," is directly contradicted by **Koch**: "The invention is direct to oxygen insufflation spectacles ... which facilitate the patient's breathing by supplying the respiratory ducts with a mixture enriched in oxygen." (Col 1, Lines 54 - 58); "[T]he oxygen is blown in only through one nostril which, otherwise, is completely closed. The patient can use the other nostril for unobstructed exhaling, while at the same time further oxygen is blown into a part of the respiratory ducts and is instantly available for, and ensures, a high oxygen concentration." Further, Applicants note that insufflation has nothing to do with breathing: the current on-line version of the Merriam-Webster Dictionary defines "insufflate" as "the act of blowing something (as a gas, powder, or vapor) into a body cavity." This is consistent with **Koch**'s anticipation of insufflating or blowing oxygen into the nose throughout the entire, normal breathing cycle.

As noted above, **Koch** does state that one advantage of the device is that while oxygen is blown into one nostril, which is otherwise closed, the patient can exhale through the other nostril. The result is that "further oxygen is blown into a part of the respiratory ducts and is instantly available for, and ensures a high oxygen concentration." (Col 2, Lines 15 - 22). However, continuing a flow of oxygen while the patient exhales during a normal cycle of inhalation and exhalation, which **Koch** teaches, is not the same as having the patient *refrain* from inhalation of the gas as Claims 1 and 103 require. **Koch** never states or suggests that the patient not inhale the gas; as the reference clearly shows, the gas is

expected to be inhaled. Further, with respect to Claims 61 and 102, **Koch** actually teaches against inhibiting the passage of the therapeutic gas into the trachea and lung -- the whole purpose of the **Koch** device is to supply the respiratory ducts with a gas mixture enriched in oxygen. (Col 1, Lines 55 - 57; Col 2, Lines 15 - 18).

Since **Koch** does not show the invention as claimed, Applicants respectfully suggest that the rejection under 35 U.S.C. § 102 is not appropriate. Claims 1, 61, 102 - 103 and their dependent claims are allowable.

E. Rejection of Claims under 35 U.S.C. § 103

Claims 6-9

The Examiner has rejected claims 6-9 as being unpatentable over **Koch**. The Examiner states that **Koch** discloses the claimed invention except for the flow rates, time range of flow, and repetitive steps.

As noted above in the discussion regarding Rejection of Claim 1, from which each of these claims depend, under 35 U.S.C. § 102, **Koch** does not show the invention as claimed. Therefore, on this ground alone, each of these claims is allowable.

Moreover, with respect to the feature of a low flow rate of between .05 cc/sec and 20 cc/sec in Claim 6, as the Examiner notes, **Koch** does not give any particular flow rate. However, such a flow rate cannot be merely a "design choice" as the Examiner suggests. As noted above, the stated purpose of the **Koch** device is to provide a "high oxygen concentration" in the mixture of air and oxygen created as the patient breathes. The average tidal value (air inhaled during a normal breath) for the human lung is about 0.5 liters and the average adult inhalation is completed in less than 2 seconds (based on 15 to 20 breaths per minute). Thus, if the **Koch** device used even the maximum flow rate claimed, only 40 cc of pure oxygen would be available to the patient per breath. Thus, the resulting mixture would be at most 27% oxygen, in comparison to 21% oxygen in air.

Applicants therefore suggest that there would be no motivation to have such a low flow rate in the **Koch** device.

With regard to time range of the flow, the **Koch** device is specifically designed for long term wear and use. One of the objectives of the device is to avoid the "disfiguring impression" that oxygen spectacles produce for long-term use (Col 1, Lines 45 - 47). Obviously, **Koch** anticipates application of a continous flow of oxygen for significantly longer 100 seconds. Thus, there is no motivation provided in **Koch** for a "design choice" of a gas for between 1 and 100 seconds as is required in Claim 7, nor repeated applications of such a flow as is required in Claims 8 and 9.

Claims 5 and 75

The Examiner has rejected Claims 5 and 75 as being unpatentable over **Koch** as applied to Claim 3, and further in view of **Zapol** (U.S. Pat. No. 5,485,827). The Examiner again states that **Koch** discloses the claimed invention. As stated above with respect to Claim 1 from which each of Claims 5 and 75 depend, **Koch** does not show the invention as claimed. Therefore, each of these claims is allowable.

Claims 4, 62-63 and 65-68

The Examiner has rejected Claims 4, 62-63 and 65-68 as being unpatentable over **Koch**, and further in view of **Fukunaga** (U.S. Pat. No. 5,983,891). The Examiner states that with regard to Claim 4 **Koch** discloses the claimed invention except for the use of carbon dioxide, which is shown in **Fukunaga**. The Examiner states that with regards to Claim 4, **Fukunaga** teaches the use of carbon dioxide, and that a motivation to combine is to provide oxygenation of the user. The Examiner further states that the selection of a gas is a matter of mere design choice and would be obvious to one of ordinary skill in the art.

In addition, the Examiner states that with respect to Claim 62, which requires that the carbon dioxide be in a carrier gas, the remaining components of the ventilatory gasses being delivered to the user function as a carrier gas in **Koch** and **Fukunaga**. Finally,

with respect to Claims 65-68, which provide for particular the Examiner reasserts his argument that flow rates, time ranges and repetitive steps are "design choices."

Applicants note that Claim 63 has been cancelled.

For the reasons set forth above with respect to Claim 1 from which Claims 62, and 65-68 depend, Applicants again assert that **Koch** does not show the invention as claimed. Therefore, each of the claims is allowable.

With regard to Claim 4, **Fukunaga** teaches an artificial ventilation system which includes a "dead space" to allow for mixture of inspiratory gases and expiratory gases, thus allowing the patient to "rebreathe" a controlled amount of expired carbon dioxide. However, while **Fukunaga** does describe the use of carbon dioxide, it, like **Koch**, describes its use solely in the context of inhalation, and thus, as noted above, does not teach or suggest the claimed invention.

Moreover, the teaching of **Fukunaga** with respect to carbon dioxide is not logically combinable with the **Koch** device. While both of the devices relate to the "respiratory arts," the context of use is quite different. The **Fukunaga** device is intended for artificial ventilation; in other words, all of the gases the patient inhales come through the ventilation device such that insuring sufficient carbon dioxide in the gases provided to the patient is essential to maintain oxygenation of the patient; having the correct balance of gases, and monitoring their effect, is critical. In contrast, the **Koch** device is intended for use by a patient who is breathing on his own with access to ambient air: during use of the **Koch** device the patient has access to carbon dioxide through the unblocked nostril. There is thus no need, and no motivation, to provide a flow of carbon dioxide to the patient. In fact, one of the major goals of the **Koch** device is increasing the oxygen enrichment available to the patient (Col. 1, Lines 48 – 50; Col. 2, Lines 18 – 22), and adding carbon dioxide to the flow of gas in **Koch** would tend to work against the stated goal.

Thus, for the reasons stated, a person of ordinary skill in the art would not be motivated to add carbon dioxide as taught in **Fukunaga** to the flow of the **Koch** device. Therefore, Claim 4 and its dependent claims 62 and 65-68 are allowable.

In addition, with respect to Claims 65 – 68, Applicants respectfully refer to their earlier arguments in connection with Claims 6-9 regarding "design choice." For the same reasons, each of claims 65-68 is also allowable.

Claims 10-12, 14-15

The Examiner has rejected Claims 10-12 and 14-15 as being unpatentable over **Koch**, and further in view of **Zimmerman** (U.S. Pat. No. 4,273,124). The Examiner states that **Koch** teaches the claimed device but does not explicitly teach allowing the flow of gas to exit by the other nostril and/or mouth. The Examiner further states that **Zimmerman** teaches this feature. He also states that a person of ordinary skill would have been motivated to combined the references so as to optimize the flow of gas and prevent the back pressure buildup in the oro-nasal/sinus cavity.

For the reasons set forth above with respect to Claim 1 from which Claims 10-12 and 14-15 depend, Applicants again assert that **Koch** does not show the invention as claimed. Therefore, each of these claims is allowable.

Further, with respect to Claims 14-15, the Examiner states that "suggested device is fully capable of adjustment of the flow rate to the patient's perceived comfort level" thus suggesting the claimed feature of adjusting the flow rate based upon the patient's comfort level. However, neither **Koch** nor **Zimmerman** suggests any kind of adjustment in flow rate – based on the patient's comfort level or otherwise. In fact, **Zimmerman** states "[t]herapeutic gas only is being inhaled into the nostril with the bulbous member at a *set flowrate* while any additional gas to supply the patient's total inhalation flow rate must enter the other nostril open to ambient air." (Col. 4, Lines 5- 9. Emphasis added.) This suggests that no adjustment to the flow rate is contemplated. Further, in both **Koch** and

Zimmerman the devices are positioned on the patient so as not to be easily removable or otherwise designed to be capable of effecting an adjustment to the flow rate.

Thus the references, even in combination, do not suggest an adjustment of the flow of gas, and Claims 14 – 15 are therefore allowable.

Claims 16, 20 - 22, 24 - 27, 69-70

The Examiner has rejected Claim 16 over **Duncan** (U.S. Pat. No. 2,860,634). The Examiner states that **Duncan** substantially discloses the claimed invention to include the release of a flow of treatment gas from a hand-held dispenser, but does not disclose the specific flow range of 0.5 cc/sec to 20 cc/sec. The Examiner repeats his argument made in connection with Claims 6-9 regarding flow rate as a "design choice."

Claim 16 has been amended to delete oxygen from the list of gases. Claim 106 has been added, which is essentially the same as Claim 16 but which claims only oxygen as the therapeutic gas. Applicants point out that **Duncan** does not teach the use of gas other than oxygen and that Claim 16 is allowable on this basis alone.

In addition, with respect to both claims 16 and newly added claim 106, applicants respectfully point out that **Duncan**, like **Koch**, teaches a device that is intended for use as an inhaler. **Duncan** includes a nose piece that fits into both nostrils, thus suggesting that the user will obtain all of the gas needed for at least one breath from the device. As discussed above with respect to Claims 6-9, the average tidal value (air inhaled during a normal breath) for the human lung is about 0.5 liters and the average adult inhalation is completed in less than 2 seconds (based on 15 to 20 breaths per minute). Thus, although **Duncan** does not disclose a specific flow rate, if the device is to be used for inhalation, logically the flow would generally have to be on the order of .25 liters/sec or about 250 cc/sec – significantly more than the low flow rate claimed. This is further supported by the fact that **Duncan** indicates that each bottle will be sufficient for only "several" treatments (Col. 3, Lines 71-72). There is thus no motivation provided in **Duncan** to have a low flow rate, given the intended use of the device for inhalation.

Further, with respect to Claim 16 as amended, while **Duncan** does suggest that the device could be used for other gases or drugs (Col. 3, Lines 73-75), **Duncan** provides no indication of the particular gases that could be used, nor any motivation to administer these gases with a low flow rate given the clear intended use of the **Duncan** device as an inhaler.

Claim 20, which depends from Claim 16, is allowable based upon the allowability of its parent claim. Also, Claim 20 includes the further limitation that the treatment gas be a therapeutic gas and a gas selected from among oxygen, nitrogen, and halogenated hydrocarbons. **Duncan** does not teach or suggest this particular combination.
Claim 69 - 70 have been amended to depend from Claim 18 and are also allowable as depending from claims 16 and 18. As now written they require that the gas flow comprise carbon dioxide in a carrier gas. In addition, in Claim 69 the carrier gas must be inert, and in Claim 70 the carrier gas must be biologically active. The Examiner has stated that the choice of the gases, in particular the choice of a biologically active versus an inert carrier gas is a mere design choice. However, the specific limitation that the gas flow be carbon dioxide with an inert or biologically active carrier gas is not taught or suggested.

Claim 21 is allowable on based on the allowability of Claim 16.

With respect to Claim 22, the Examiner states that the device disclosed by **Duncan** is capable of sealing against a patient's mouth, and further states that nasal and oral patient airway interfaces are interchangeable mechanical equivalents in the art. However, although it might be possible to use the **Duncan** device in the mouth, the device is specifically designed for use in the nostrils, and nothing in the reference suggests any other use.

With respect to Claims 24 - 27, the Examiner essentially repeats his arguments regarding flow rates and time ranges for delivery made in connection with Claims 6-9. As was the

case with the **Koch** reference, the **Duncan** device is simply not designed for the claimed flow rate or time ranges. As with **Koch**, the **Duncan** device is designed for inhalation. Thus, for the reasons set forth with respect to **Koch** including the well-known facts regarding human respiration, the flow rate is neither taught nor suggested. In addition, it is clear that the **Duncan** device can only be used for "several" applications -- or inhalations. Thus, given the flow necessary to allow inhalation as the **Duncan** device intends, it is rather unlikely -- given a handheld device -- that the required flow could be maintained for 100 seconds. Finally, with respect to Claim 27, there is no provision in **Duncan** for any adjustment of the flow rate. (See, for example, Col. 3, Lines 49 - 34.) Thus, the adjustment limitation of Claim 27 cannot be taught or suggested by **Duncan**.

Claim 76

The Examiner has rejected Claim 76 as being unpatentable over **Duncan** as applied to Claim 16 and further in view of **Zapol** (U.S. Pat. No. 5,485,827). As a dependent claim, Claim 76 is allowable for the reasons set forth in the discussion of Claim 16. It should be noted that **Zapol** specifically teaches inhalation. The low flow rate is neither taught nor suggested by the reference.

Claims 17-18

Although not specifically discussed in the Office action, applicants respectfully suggest that, for the reasons set forth above in the discussion of Claim 16, the references to do not teach or suggest the combination of the features of the stated low flow rate with a flow of CO_2 or a flow of CO_2 in a carrier gas, as set forth in Claims 17 and 18. Both claims are therefore allowable.

Claim 92

Applicants acknowledge the Examiner's statement regarding the allowability of Claim 92 if rewritten in independent form.

4. Conclusion

For the reasons set forth above, applicants respectfully request reconsideration and allowance of all claims.

Respectfully submitted,

Date: May 12, 2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary

Application No.	Applicant(s)
09/614,389	Rasor et al.
Examiner	**Art Unit**
Joseph Weise	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Sep 24, 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-12, 14-18, 20-22, 24-27, 61-63, 65-72, 74-76, 92, 102, and* is/are pending in the application.

4a) Of the above, claim(s) *71, 72, and 74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-12, 14-18, 20-22, 24-27, 61-63, 65-70, 75, 76, 102, and 103* is/are rejected.

7)☒ Claim(s) *92* is/are objected to.

8)☒ Claims *71, 72, and 74* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of claims 1, 3-12, 14-18, 20-22, 24-27, 61-63, 65-72, 74-76, 92, 102-103 in Paper No. 10 is acknowledged. However, the election/alignment of the newly added claims is in error. Claim 71 depends upon claim 19, a non-elected claim, hence claim 71 is also non-elected. Claims 72 & 74 depend upon claim 28, also a non-elected claim, hence claims 72 & 74 arc also non-elected.

Claim Rejections - 35 USC § 112

2.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10, 20, 69 & 102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to the use of "and/or" in claim 10, it renders the claim scope indefinite because it is unclear if applicant intends one or the other or both to be the scope of the claim.

In regards to claim 20, the claim is dependent upon claim 19, which is now canceled, thus rendering the claim indefinite. The claim is presumed to depend upon claim 16 for examination purposes.

4. Claim 69 recites the limitation "the carrier gas " in line 1. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 102 recites the limitation "the passage" in line 5. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 102 recites the limitation "the trachea" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

7. Claim 63 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 62. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 61 & 102-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Koch (US 4465067).

In regards to claims 1, 3, 61 & 102-103, Koch discloses a method for delivering therapeutic gas to a person having a nasal/oral mucous membrane, said method comprising the generation of a flow of therapeutic gas (via conduit 8), infusion of the nasal or oral mucous

membranes (note that by dint of anatomy alone of the oronasal cavity both cavities will be infused when gas is nasally delivered) with the flow of therapeutic gas (note the nasal interface) wherein the person refrains from inhaling (note that the gas is delivered to insufflate the oronasal cavity, hence delivery is not primarily for breathing but insufflation, if the user where to breath the gas could not insufflate the nasal cavity). In regards to claims 61/102/103 this refrainment of breathing to facilitate insufflation would result in inhibition of the passage of the gas into a user's trachea & lungs.

In regards to claim 3, Koch discloses the use of oxygen.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch.

In regards to claim 6, in regards to the flow rate range of 0.5 cc/sec to 20 cc/sec, Koch substantially disclose the claimed invention except for this flow rate range.

It is noted that applicant's specification does not set forth this flow rate range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 7, in regards to the time range of 1 sec to 100 sec for delivery, the reference noted above substantially disclose the claimed invention except for this flow rate range.

It is noted that applicant's specification does not set forth this time range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 8 & 9, where in applicant repeats the infusion time period set, the reference noted above substantially disclose the claimed invention except for this repetition, i.e. duplication of a known step for a known purpose.

It is noted that applicant's specification does not set forth this duplication, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

12. Claims 5 & 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch as applied to claim 3 above, and further in view of Zapol (US 5485827).

Koch substantially discloses the instant application's claimed invention, but does not explicitly disclose use of a carrier gas. However, Zapol disclose such (col. 7 lines 25-35). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Zapol and used them with the device of Koch. The suggestion/motivation for doing so would have been to minimize secondary reactants among the gases delivered to the user. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

In regards to claim 75, the suggested device discloses the use of nitric oxide as the therapeutic gas the carrier gas is non-oxidizing and they blend to form diluted nitric oxide gas (see Zapol col. 7 lines 20-25).

13. Claims 4, 62-63 & 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch in view of Fukunaga (US 5983891).

In regards to claim 4, Koch substantially discloses the instant application's claimed invention, but does not explicitly disclose the therapeutic gas consisting essentially of Carbon Dioxide. However, Fukunaga disclose such (See Summary of Invention discussing capinia modes of gas deliver). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Fukunaga and used them with the device of Koch. The suggestion/motivation for doing so would have been to

promote the oxygenation of the user. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 62 & 63, Fukunaga discloses the carbon dioxide gas being in a carrier gas (the remaining components of the ventilatory gasses being delivered to the user).

In regards to claim 65, in regards to the flow rate range of 0.5 cc/sec to 20 cc/sec, the reference noted above substantially disclose the claimed invention except for this flow rate range.

It is noted that applicant's specification does not set forth this flow rate range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 66, in regards to the time range of 1 sec to 100 sec for delivery, the reference noted above substantially disclose the claimed invention except for this flow rate range.

It is noted that applicant's specification does not set forth this time range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claims 67 & 68, where in applicant repeats the infusion time period set, the reference noted above substantially disclose the claimed invention except for this repetition, i.e. duplication of a known step for a known purpose.

It is noted that applicant's specification does not set forth this duplication, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

14. Claims 10-12, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch as applied to claims 1/102 above, and further in view of Zimmerman (US 4273124).

In regards to claim 10, Koch substantially discloses the instant application's claimed invention, but does not explicitly disclose allowing the flow to exit another nostril and/or the mouth. However, Zimmerman disclose such (See the abstract last line, note figs 6-8 and supporting text). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Zimmerman and used them with the device of Koch. The suggestion/motivation for doing so would have been to optimize

the flow of gas and prevent the back pressure buildup in the oro-nasal/sinus cavity. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 11, the suggested device discloses that all gas goes through the "exhaust" nostril when the mouth is closed (See figs 5 & 6 and supporting text).

In regards to claim 12, the suggested device noted above substantially disclose the claimed invention except for the reversal or rearrangement of gas input through the mouth and out the nasal passage(s).

It is noted that applicant's specification does not set forth this reversal or rearrangement, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 14, the suggested device is fully capable of adjustment of the flow rate to the patient's perceived comfort level, the

In regards to claim 15, decrease of flow rate resulting in increase of treatment time obvious to one of skill in the art because flow reduction means less therapeutic gas is being delivered to a patient and hence it will take more time to deliver the same dose to the patient to achieve the same therapeutic result.

15. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan (US 2860634).

In regards to claim 16, Duncan substantially discloses the instant application's claimed invention to include the release from a hand held dispenser (See Fig 2) a flow of treatment gas comprising oxygen, but does not explicitly disclose the specific flow range of 0.5 cc/sec to 20 cc/sec.

It is noted that applicant's specification does not set forth this flow rate range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claims 20, 69-70, Duncan substantially discloses the instant application's claimed invention to include the use of other gases, liquids or drugs than oxygen, but does not disclose the use of a carrier gas that is biologically active. However one of skill would view that in light of this teaching of Duncan and the state of the art that the use of a carrier gas that is inert/biologically active is obvious e.g. a composite gas that uses an inert carrier gas such as "air" which has the inert carrier gas of nitrogen but which is also a biologically active material.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 21, Duncan discloses the dispenser as being suitable for sealing against the user's nasal passages.

In regards to claim 22, Duncan discloses the dispenser that is fully capable of sealing against a user's mouth. Furthermore nasal and oral patient airway interfaces are known interchangeable mechanical equivalents in the art (see Fukunaga).

In regards to claim 24, in regards to the time range of 1 sec to 100 sec for delivery, the reference noted above substantially disclose the claimed invention except for this flow rate range.

It is noted that applicant's specification does not set forth this time range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claims 25 & 26, where in applicant repeats the infusion time period set, the reference noted above substantially disclose the claimed invention except for this repetition, i.e. duplication of a known step for a known purpose.

It is noted that applicant's specification does not set forth this duplication, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 27, in regards to the flow rate range of 0.5 cc/sec to 20 cc/sec, the reference noted above substantially disclose the claimed invention except for this flow rate range.

It is noted that applicant's specification does not set forth this flow rate range, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

16. Claim 76 rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan as applied to claim 16 above, and further in view of Zapol (US 5485827).

Duncan substantially discloses the instant application's claimed invention, but does not explicitly disclose use of nitric oxide as the therapeutic gas, a carrier gas that is inert and non-oxidizing and which form a diluted mixture of nitric oxide. However, Zapol disclose such (col. 7 lines 25-35). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Zapol and used them with the device of Duncan. The suggestion/motivation for doing so would have been because Duncan discloses the use of composite therapeutic gases (col. 3 lines 65-75) and Zapol discloses the use of a composite gas for therapeutic treatments (col. 7 lines 20-35). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Allowable Subject Matter

17. Claim 92 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not anticipate or suggest the method step of mixing reagents to produce carbon dioxide for capinia respiratory therapy.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5908870, 5562644, 4934359 .

Yoga Cure for Headaches, YogaJournal.com Jan/Feb 1999; Yoga: A Cure for Headaches, May 2001; Yoga Rx for Headaches, Yogabasics.com 2001; Can't stop the Pain 13 Jun 2001, Abcnews.com; Oxygen Therapy for Headaches www.headaches.com 2002; Smoking Cessation: New strategies and opportunities for pharmacists. American Druggist, Jan 1997; Intranasal fenoterol in asmatic subjects: An alternative route of administration, J. Of Clinical Immunology Oct 1984; Zysk: The Science of Respiration and the doctrine of the bodily winds in ancient India, J. Of American Oriental Society 113.2 (1993).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

JFWeiss

December 8, 2002

Aaron J. Lewis
Primary Examiner